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Office of Nutritional Products Labeling and Dietary Supplements (HFS-810) Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 5100 Paint Branch Pkwy. College Park, MD 20740

RE: Notification of statements on a dietary supplement known as. Chito-Maxx™

October 6, 2003

Dear Ladies/Gentlemen:

Pursuant of 21 C.F.R. Subpart F, section 101.93, Body Wise International, Inc. ("Body Wise" the distributor, which is located at 2802 Dow Avenue, Tustin, CA 92780) wishes to notify the Food and Drug Administration that it has commenced marketing a dietary supplement known as Chito-Maxx<sup>™</sup> which includes statements of nutritional support in it's labeling.

The following statements are being made for the dietary supplement known as Chito-Maxx™

- Chitosan. It helps support healthy lipid levels that are already within the normal range and controls weight naturally.
- Studies show that chitosan acts like a fiber sponge, absorbing many times its own weight in undigested fat. When combined with vitamin C and inulin analog, the effect is multiplied and your hunger pangs diminish.
- Chitosan Fat binding fiber that may decrease dietary fat absorption.
- Inulin Analog Provides energy over extended periods and may help maintain healthy blood sugar and insulin levels that are already within the normal range.
- Chito-Maxx<sup>™</sup> supports the digestion of fat.
- Vitamin C Supports a healthy immune system function and potentiates chitosan's fat-absorbing action.
- Chito-Maxx<sup>™</sup> supplies a patented ingredient, called chitosan, a fat-binding fiber that may decrease dietary fat absorption.

The above statements are accompanied by the required disclaimer, which is prominently displayed in a box in boldfaced type.

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The information contained in this notice is complete and accurate. Body Wise maintains on file substantiation that these statements are truthful and non-misleading.

An original and two copies of this notification are being submitted.

Sincerely,

Alan E. Huffington

**Director of Regulatory Affairs** 

dw/AEH

Enclosures: Two copies of this two-page letter.